

Food and Drug Administration, HHS

§ 880.2910

both the support and the patient, devices where the patient is lifted by a sling from a bed to be weighed, and devices where the patient is placed on the scale platform to be weighed. The device may be mechanical, battery powered, or AC-powered and may include transducers, electronic signal amplification, conditioning and display equipment.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 880.9.

[45 FR 69682, Oct. 21, 1980, as amended at 61 FR 1123, Jan. 16, 1996; 66 FR 38803, July 25, 2001]

§ 880.2740 Surgical sponge scale.

(a) *Identification*. A surgical sponge scale is a nonelectrically powered device used to weigh surgical sponges that have been used to absorb blood during surgery so that, by comparison with the known dry weight of the sponges, an estimate may be made of the blood lost by the patient during surgery.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9. The device also is exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

[45 FR 69682, Oct. 21, 1980, as amended at 66 FR 38804, July 25, 2001]

§ 880.2800 Sterilization process indicator.

(a) *Biological sterilization process indicator*—(1) *Identification*. A biological sterilization process indicator is a device intended for use by a health care provider to accompany products being sterilized through a sterilization procedure and to monitor adequacy of sterilization. The device consists of a known number of microorganisms, of known resistance to the mode of sterilization, in or on a carrier and enclosed in a protective package. Subsequent

growth or failure of the microorganisms to grow under suitable conditions indicates the adequacy of sterilization.

(2) *Classification*. Class II (performance standards).

(b) *Physical/chemical sterilization process indicator*—(1) *Identification*. A physical/chemical sterilization process indicator is a device intended for use by a health care provider to accompany products being sterilized through a sterilization procedure and to monitor one or more parameters of the sterilization process. The adequacy of the sterilization conditions as measured by these parameters is indicated by a visible change in the device.

(2) *Classification*. Class II (performance standards).

§ 880.2900 Clinical color change thermometer.

(a) *Identification*. A clinical color change thermometer is a disposable device used to measure a patient's oral, rectal, or axillary (armpit) body temperature. The device records body temperature by use of heat sensitive chemicals which are sealed at the end of a plastic or metal strip. Body heat causes a stable color change in the heat sensitive chemicals.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9.

[45 FR 69682, Oct. 21, 1980, as amended at 61 FR 1123, Jan. 16, 1996; 66 FR 38804, July 25, 2001]

§ 880.2910 Clinical electronic thermometer.

(a) *Identification*. A clinical electronic thermometer is a device used to measure the body temperature of a patient by means of a transducer coupled with an electronic signal amplification, conditioning, and display unit. The transducer may be in a detachable probe with or without a disposable cover.

(b) *Classification*. Class II (performance standards).